

**REMARKS**

After entry of this amendment, claims 1-16, 27, 29-46, 49-54, 58, 59, 64, 65, 67, 72, 73, and 75-87 will be pending for the Examiner's review and consideration. Claims 1, 2, 45, 50, and 81 have been amended. No new matter has been added. Claims 47, 48, 55-57, 60-63, 66, 68-71, and 74 have been canceled. Claims 17-26 were previously canceled as subjected to a non-elected species. Claims 14, 42, 63, and 71 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

This amendment responds to the office action mailed April 28, 2004. In the office action the Examiner:

- objected to claim 81 as depending from claim 76;
- rejected claims 1, 11, 15, 27, 29-36, 39-41, 43, 55-59, 64, 75, and 81-85 under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,379,363 to Herrington ("Herrington");
- rejected claims 1-6, 8-9, 11, 15, 27, 29-34, 36, 39-41, 43, 45-56, 58-59, 65-67, 73-75, 77-82, and 85-87 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,800,436 to Lerch ("Lerch");
- rejected claims 12-13, 16, 37-38, 44, 60-62, 64 and 76 under 35 U.S.C. § 103(a) as being unpatentable over Herrington;
- rejected claims 7, 10, 12-13, 16, 35, 37-38, 44, 57, 60-62, 64, 68-70, 72, 76, 83, and 84 under 35 U.S.C. § 103(a) as being unpatentable over Lerch; and
- objected to claims 14, 42, 63, and 71 as being dependent upon a rejected base claim, but otherwise allowable if rewritten in independent form.

**Claim 81**

Claim 81 was objected to as depending from claim 76. Specifically, the Examiner stated that claim 81 did not further limit claim 76 and thus claim 81 should depend from claim 75 rather than claim 76. In accordance with the Examiner's suggestion, claim 81 has been amended to depend from claim 75. Thus, withdrawal of this rejection and allowance of claim 81 is respectfully requested.

**Independent Claim 1**

The Applicant would first like to thank the Examiner for the allowance of the subject matter disclosed in claims 14, 42, 63, and 71 if rewritten in independent form. Independent claim 1 has been amended to include substantially all of the limitations of allowable claim 14 including intervening claims. It should be noted, however, that independent claim 1 was not amended to recite "wherein the extension member is a ribbon" as, it is respectfully submitted, that such limitation is not required to read over the cited prior art.

Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Claims 50-54, 58, 59, 64 and 65 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 50-54, 58, 59, 64 and 65 is therefore respectfully requested.

**Independent Claim 2**

Independent claim 2 was rejected under 35 U.S.C. § 102(b) as being anticipated by Lerch. Independent claim 2, as amended, recites, *inter alia*, a cranial flap clamp comprising a first clamping member, a substantially smooth extension member extending from the first clamping member, and a second clamping member wherein the second clamping member is fixed with respect to the extension member by a crimping force applied to the extension member adjacent the second clamping member. There is no disclosure, teaching, or suggestion in Lerch of applying a crimping force to the extension member adjacent to the second clamping member to fix the second clamping member with respect to the extension member. Rather, Lerch discloses a pin 11 and two disks 21, 22 wherein the second disk 22 is fixed to the pin 11 by a tool of the type to fasten blind rivets and/or a threaded nut 112b. Therefore, it is respectfully submitted that independent claim 2 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 2 is respectfully requested.

Claims 3-10, 67, 72, and 73 all ultimately depend from independent claim 2, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 3-10, 67, 72, and 73 is therefore respectfully requested.

#### Independent Claim 11

Independent claim 11 was rejected under 35 U.S.C. § 102(e) as being anticipated by Herrington. Alternatively, independent claim 11 was rejected under 35 U.S.C. § 102(b) as being anticipated by Lerch. Independent claim 11 recites, *inter alia*, a cranial flap clamp comprising a first clamping member, an extension member, and a second clamping member wherein at least one of the clamping members has a plurality of radial cutouts extending radially inwards from an outer circumference of the member, the radial cutouts being configured to allow the clamping member to at least partially conform to the outer surface of the bone flap and skull. There is no disclosure, teaching, or suggestion in either Herrington or Lerch of a clamping member having a plurality of cutouts extending radially inwards from the outer circumference of the member to permit the member to at least partially conform to the outer surface of the bone flap and skull. Rather, Herrington discloses a disk 12 and a cap 14, wherein the disk 12 and cap 14 include a plurality of rectangular shaped bores 26 passing therethrough in order to reduce the overall mass of the clamp as well as to permit passage of fluid and bony ingrowth. Moreover, Herrington discloses the incorporation of a plurality of heart-shaped bores 60 to form a plurality of resilient fingers 54 so that the resilient fingers can engage annular ridges 32 formed on the stem 16 for securing the cap 14 with respect to the stem 16. See Herrington at Figure 3, and at column 4, line 59 to column 5, line 17. It is respectfully submitted that there is absolutely no disclosure in Herrington of providing a plurality of cutouts extending radially inwards from the outer circumference of the member. Moreover, there is absolutely no disclosure in Herrington of providing a plurality of cutouts extending radially inwards from the outer circumference of the member to permit the member to at least partially conform to the outer surface of the bone flap and skull. In fact, Herrington discloses the exact opposite, Herrington discloses heart shaped bores 60 that extend from a central opening outwards toward the outer circumference but which never reach the outer circumference. That is because the heart shaped bores are designed to permit the fingers to be flexible so that they can engage the stem in a ratchet-type mechanism. If the heart shaped bores extended to the outer circumference of the disk then the fingers would be structurally unsupported.

Similarly, Lerch discloses a pin 11 and two disks 21, 22, wherein the disks 21, 22 can be provided with slits 214 extending radially outward from a central hole 211. Alternatively, the disks 21, 22 can be provided with perforations 226 between the central hole and its circumference in order to conserve material and decrease weight. See Lerch at Figures 2 and 3 and at column 3, lines 1-13. It is respectfully submitted that there is absolutely no disclosure in Lerch of providing a plurality of cutouts extending radially inwards from the outer circumference of the member. Moreover, there is absolutely no disclosure in Lerch of providing a plurality of cutouts extending radially inwards from the outer circumference of the member to permit the member to at least partially conform to the outer surface of the bone flap and skull.

Therefore, it is respectfully submitted that neither Herrington or Lerch, either alone or in combination, disclose, teach, and/or suggest all of the limitations of independent claim 11. Thus, it is respectfully submitted that independent claim 11 is allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claim 11 is respectfully requested.

Claims 12-16 and 75-85 all ultimately depend from independent claim 11, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 12-16 and 75-85 is therefore respectfully requested.

#### Independent Claim 27

Independent claim 27 was rejected under 35 U.S.C. § 102(e) as being anticipated by Herrington. Alternatively, independent claim 27 was rejected under 35 U.S.C. § 102(b) as being anticipated by Lerch. Independent claim 27 recites, *inter alia*, a cranial flap clamp comprising a first clamping member, an extension member, and a second clamping member wherein the portions of the first and second clamping members that abut the surfaces of the bone flap and skull are substantially smooth. There is no disclosure, teaching, or suggestion in either Herrington or Lerch of a clamping member having the surfaces that abut or contact the bone flap and skull be substantially smooth. To the contrary, as explicitly stated, Herrington discloses a disk 12 and a cap 14, wherein the disk 12 and cap 14 include "a plurality of scalloped protrusions 52 which fixedly engage or contact the outer cranial flap and skull to rigidly retain one relative to the other." See Herrington at Figure 1, 2, and at column 4, lines 55-58. It is respectfully submitted that Herrington teaches away from the device of claim 27 and that there is absolutely no disclosure in Herrington of providing a first clamping member and a second clamping member, wherein the portions of the first and

second clamping members that abut the surfaces of the bone flap and skull are substantially smooth.

Similarly, Lerch discloses a pin 11 and two disks 21, 22, wherein the disks 21, 22 contain a "row of teeth 213 extend[ing] along the edge 212 of the concave side of disk 21, and a row of teeth 223 extend[ing] along the edge 222 of the concave side of disk 22." The disks 21 and 22 being forced together "until the teeth on each disk bite into the tissue of the plug and of the residual cranium, securing the two together." See Lerch at Figures 1-6, at column 2, lines 62-64, and column 3, lines 35-39. It is respectfully submitted that Lerch also teaches away from the device of claim 27 and that there is absolutely no disclosure in Lerch of providing a first clamping member and a second clamping member, wherein the portions of the first and second clamping members that abut the surfaces of the bone flap and skull are substantially smooth.

Therefore, it is respectfully submitted that neither Herrington or Lerch, either alone or in combination, disclose, teach, and/or suggest all of the limitations of independent claim 27. Thus, it is respectfully submitted that independent claim 27 is allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claim 27 is respectfully requested.

Claims 29-44, 86, and 87 all ultimately depend from independent claim 27, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 29-44, 86, and 87 is therefore respectfully requested.

#### Independent Claim 45

Independent claim 45 was rejected under 35 U.S.C. § 102(b) as being anticipated by Lerch. Independent claim 27, as amended, recites, *inter alia*, a cranial flap clamp comprising a first clamping member, a substantially smooth extension member extending from the first clamping member, and a second clamping member, the second clamping member having a plurality of radial cutouts extending from an outer circumference of the member; and an integrally formed stop on the extension member provided by twisting and shearing of the extension member at a surgeon selected location along its length for limiting movement of the second clamping member on the extension member. As previously described, there is no disclosure, teaching, or suggestion in Lerch of a clamping member having a plurality of radial cutouts extending inward from an outer circumference of the member. Moreover, there is no disclosure, teaching, or suggestion in Lerch of an integrally formed stop on the extension member provided by twisting and shearing of the extension member. Rather, Lerch discloses

a pin 11 and two disks 21, 22 wherein the second disk 22 is fixed to the pin 11 by a tool of the type to fasten blind rivets and/or a threaded nut 112b. Therefore, it is respectfully submitted that independent claim 45 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 45 is respectfully requested.

Claims 46 and 49 all ultimately depend from independent claim 45, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 46 and 49 is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-16, 27, 29-46, 49-54, 58, 59, 64, 65, 67, 72, 73, and 75-87 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

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Respectfully submitted,

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